GOVERNMENT OF ANDHRA PRADESH

ABSTRACT

Health, Medical and Family Welfare – Branded Generic Medicines (Allopathic) centralized procurement, establishment, of outlets- to make available of High quality branded Generic Medicines at affordable prices and ensure accessibility to all citizens – Orders – Issued.

HEALTH, MEDICAL & FAMILY WELFARE (H2) DEPARTMENT

G.O.Ms.No:49 Dated:19.05.2015

Read the following :-

1. G.O.Ms.No.54 HM&FW (L2) Dept., dt:14.03.2011.
2. Lr.Rc.No.20/Ph5/MW/GM/2013-14 dt:20.12.2013 of APMSIDC.
3. Lr.No.335/M1/2014-1 dt:24.01.2014 of the Principal Secretary, HM&FW (M1) Department.
4. From the MD, APMSIDC, A.P., Hyderabad, File No.26 /Jeevanadhara/PH5/2014-15, dt:27.04.2015.

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O R D E R:

In the Government order 1st read above, wherein orders were issued improving of Access to Quality Generic Medicines at fair prices establishment of Generic Medicine retail outlet.

2. In the letter 4th read above, the MD, APMSIDC has submitted the proposals stating that certain research studies have revealed that the State's current annual health care costs are about five per cent of the Gross State Domestic Product (GSDP), of which at least sixty percent is the cost of medicines. Further, medicines are being retailed through more than 50,000 pharmacy outlets spread across the state, which has been posing practical challenges in terms of ensuring quality standards. Moreover, irrational use of medicines, especially indiscriminate and excessive use of antibiotics, has been on the increase. Despite achieving a strong capability for the manufacture of quality branded and generic medicines in most therapeutic categories, the citizens of the state are unable to access quality medicines at reasonable price.

3. In 1947, India's pharmaceutical market was dominated by Multinational companies that controlled between 80 to 90 percent of the market primarily through imports. The total turnover was Rs.10 Crore. Ninety nine percent of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world.

4. The number of domestic pharmaceutical firms expanded dramatically from negligible to more than 17,000 in 2014. India has the world's third-largest API'S (Active Pharmaceutical Ingredients) manufacturing industry, producing more than 400 different API'S and accounting for approximately 12 percent of the world's API production. India is producing Rs. 1,70,000 cr (approximately) worth of Medicines and Exporting Rs.90,000 Cr to U.S., Europe and other Developed and Developing countries.

5. Indian pharmaceutical companies now supply nearly all the country's demand for formulations. They produce nearly 60,000 generic brands in 60 therapeutic categories. Nearly 97 percent of India's drug market consists of second-and-third generation drugs, which are no longer subject to patent protection in the developed world.

6. According to a World Bank report, 34.7%, or 35 million Indians live on less than U.S. $1 per day. As a result, affordability of medicines is often beyond the reach of a majority of the population. However, these costs only accounts for the price of medicine, consultation fees of the doctor and diagnostic tests may lead to a considerably higher total cost for the patient in private sector.

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7. According to World Medicine Report of WHO, in India majority of the population lacks access to essential medicines and there is a huge gap between production of medicines and access to medicines**.** 80% of health care is financed by out-of-pocket by the patients and their families. Thus, the price of medicines is a crucial determinant of the health of citizen. It is also a fact that 65% out of pocket expenditure on health care is being incurred because of purchase of medicines.

8. Since, India has one of the highest private spending in healthcare as compared to other countries, the use of generic drugs can add up to marked savings for everyone in general but particularly for the elderly who generally take more medications than the young and have less income.

WHAT IS A " DRUG "

Section 3(b) of Drugs and Cosmetics Act, 1940 defines a " Drug " as "all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes".

WHAT IS GENERIC DRUG

W.H.O defines "A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights".

Generic drugs are copies of off-patent brand-name drugs that come in the same dosage, safety, strength, and quality and for the same intended use. Generic name is the pharmacological name of the compound assigned either by WHO's International Non-proprietary Names Committee or by the USA adopted Name Council. Drugs whose patents have expired are also included in the category of generics. These drugs are then sold under their chemical names as both over the counter and prescription forms. They are referred to as an unbranded formulation.

WHAT IS BRAND NAME

"A brand name is a name given to a drug by the manufacturer. The use of the name is reserved exclusively for its owner". Brand name drugs are innovator drugs patented by pharmaceutical companies to prevent them from being copied or reverse engineered by other companies.

BRAND VS GENERIC

The Drugs and Cosmetics Act, 1940, an Act regulating and enforcing the Standard of Drugs in this Country made no distinction between the brand and generic drugs. As such both have to comply with all the parameters prescribed under the Act. Which means that the drugs of the same composition and indication whether available in brand or generic names are of Standard Quality as long as they comply with the specifications/standards prescribed under the Act.

BRAND VS GENERIC – INDIAN CONTEXT

As per the W.H.O definition, "a branded medicine is the one which is produced by the innovator; and a generic medicine is the one which is an equivalent and which is produced by companies other than the innovator company". When seen from this angle, ALMOST all medicines produced in this country are generic equivalents. Branded generics are unpatented drugs sold under a "Brand Name".

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"Branded-generics" more closely resemble what are globally referred to as 'generics'. Branded-generic manufacturers sometimes choose not to market the medicines themselves, instead selling their medicines at a much lower rate to a distributor, who in turn sells to retail shops.

Branded-generic medicines have less name recognition, and it falls on the retail pharmacy to promote the medicine. The retail profit is larger and varies from 50% to 1000-2000%.

The Government orders 1st read above certain guidelines were issued to establish Generic Medicines wherein the following shortcomings are noticed:-

1. Non availability of uniform list of medicines in retail outlets.
2. Different price for the same medicine in different retail outlets as procurement was from local wholesaler at varied price.
3. Irregular timings of the shops.
4. Retail outlets not strategically located.
5. Lack of awareness in general public due to absence of Publicity.
6. Doctors not prescribing the Generic medicines.
7. No assurance for quality.
8. Absence of logistic management.
9. Slender margins, leading to low income, poor wages and weak manpower.

The Government is committed to overcome all these shortcomings and create a robust structure in place to ensure that the intended goals are delivered effectively.

VISION / GOAL

TO MAKE AVAILABLE HIGH QUALITY BRANDED GENERIC MEDICINES AT AFFORDABLE PRICES AND ENSURE ACCESSIBILITY TO ALL CITIZENS.

Government after careful examination hereby issues the following guidelines to facilitate streamlined implementation of the scheme and promote the prescription of generic medicines professionals and their use by the public at large:-

STRATEGY:

1. **Preparation of a comprehensive list of medicines to be made available in all retail outlets uniformly.**

List of Medicines shall be prepared by t he APMSIDC and to approve by the SLSEC (state level standing Expert Committee), so as to meet the objectives that address the priority health care requirements of a given population. These medicines shall be selected through an evidence-based process with due regard to public health relevance, quality, safety, efficacy and comparative cost-effectiveness. The fundamental criteria for essential medicines are that they shall be available at all the generic outlets as per need, in suitable quantities and dosage forms.

2. Procurement

The responsibility of procurement of branded generic medicines is entrusted to Andhra Pradesh Medical Services Infrastructure Development Corporation. This will enable centralized procurement of Medicines and surgical consumables and to get the benefit of economy of scale as well as to ensure uniform pricing throughout the state.

3. Maintenance

Self help groups, Mandal samakhyas, Zilla Samakhyas and MEPMA town level Federation samakhyas and offer agencies shall be encouraged to set up the retail generic medicine stores.

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4. Storage

APMSIDC shall follow appropriate storage protocols to ensure that the efficacy of the medicine is not lost and for effective inventory management. Additional Godowns over and above the existing Central medicine stores will be constructed or hired private godowns as per availability and suitability.

5. Quality Control

Ensuring quality of the medicines is one of the prime objectives. Accordingly to ensure quality of the highest order, APMSIDC will conduct quality test in a time bound manner. A double blinded method of coding the samples shall be followed to maintain absolute confidentiality and testing them as per IP norms.

6. Location

Selecting strategic location for the retail outlets and providing necessary infrastructure is the key to success of the outlet. They must be centrally located and accessible to large sections of the population. The District Collector shall identify suitable sites for the establishment of retail generic stores leveraging various government and semi government facilities available in strategic locations wherever possible.

7. Ensuring viable margins.

The retail outlets should be given appropriate margins to ensure their viability, which shall be approved by the SLSEC. The margins shall be built in the final selling price which shall be uniform throughout the state.

8. Online supply chain management system.

Comprehensive information system shall be established to manage the entire cycle of procurement and supply chain management.

9. Statutory Permissions.

All outlets will have to fulfill the statutory requirements of the AP Drug Control Administration. The Director General of Drug Control Administration shall facilitate the licensing process in a fixed timeframe by fixing the responsibility to all Drug Inspectors located in each district.

10. Nodal Agency

APMSIDC will be the nodal agency for implementation of this project. A dedicated team shall be set up to implement this scheme. The administrative and management cost shall be as is in the case of existing drug procurement policy of APMSIDC. APMSIDC shall facilitate the Government in issuing further guidelines and circulars that are necessary to achieve its intended goal.

11.Sensitizing doctors

The Managing Director of APMSIDC shall organize a series of workshops for the medical professionals working in the government as well as the private sector across the state in collaboration with the medical and specialist associations.

12. Monitoring Mechanism

CEO SERP and MD, MEPMA shall carryout selection, capacity building of Samakhyas / town level federations, APMSIDC shall evolve and implement an effective monitoring mechanism. They shall put in place a mechanism to ensure that sufficient stocks are always available in the shops and all accounts are upto date through an online accounting system.

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13.Funding

Government shall create a Revolving Fund of Rs. 50 crores for APMSIDC to facilitate the procurement operations and timely payments for the purchases made, Logistics including storage and transportation, Administration and IEC activities.

Government hereby constitute the following committees to facilitate streamlined implementation of the scheme and to promote the prescription of branded generic medicines by the medical professionals and their use by the public large:-

A.State Level Standing Expert Committee.

Sl. No	Official Designation	Designation in the Committee
1	Special Chief Secretary (HM&FW) Dept.	Chairman
2	Principal Secretary (Primary Health) HM&FW Dept.,	Co-Chairman
3	Managing Director, APMSIDC	Member - convener
4	Commissioner of Health & FW	Member
5	Director General, DCA	Member
6	CEO SERP	Member
7	MD, MEPMA	Member
8	PO, ITDA	Member
9	Director of Public Health & Family welfare	Member
10	Director of Medical Education	Member
11	Commissioner, APVVP	Member
12	Executive Director of Pharma Export Council	Member
13	Senior Professor of Pharmacology in the State	Member
14	State President of IMA	Member
15	Any Technical Expert to be nominated by Govt.	Member

The State Level Committee shall meet once in 3 months to review establishment of generic drug stores and monitor the performance of the existing generic medicine stores in the state.

B. District Level Committee:

S.No.	Official Designation	Designation in the Committee
1	District Magistrate & Collector	Chairman
2	Addl. Joint Collector	Member
3	District Medical & Health officer	Member

4	Superintendent of District / Teaching Hospital	Member
5	Principal of the Medical / Dental College	Member
6	Dist. Co-coordinator of Hospital Services	Member
7	Project Director of DRDA / IKP	Member / Convener
8	Three representatives of District Samakhyas	Member
9	Asst. Director / Drug Inspector (DCA)	Member
10	Head of the Department of Pharmacology	Member
11	Representative of IMA	Member
12	Municipal Commissioner	Member
13	Any other member nominated by the District Collector	Member

The District Level Committee should meet once in every month to review and approve the establishment of new branded generic out lets and to monitor the functioning of the existing generic medicine outlets, take measures to popularize the use of Generic medicines through periodic campaigns and awareness camps and furnish comprehensive reports to the state level committee.

C. Technical Bid Evaluation Committee

Sl. No	Official Designation	Designation in the Committee
1	Director General, Drugs Control Administration	Chair person
2	Nominee of the M.D, APMSIDC	Member / Convener
3	Commissioner of Health & Family Welfare	Member
4	Director of Public Health & Family Welfare	Member
5	Commissioner of APVVP	Member
6	Director of Medical Education	Member

The Committee shall be responsible for the following:

i) To scrutinize pre-qualification bids received pursuant to any tender for Procurement of medicines and accept or reject the bids.

ii) To inspect or cause inspection of the manufacturing facilities of bidders.

D. Commercial Bid Evaluation Committee

SlNo	Official Designation	Designation in the Committee
1	Special Chief Secretary to the Government	Chair person
2	Managing Director, APMSIDC	Member / Convener

3	Commissioner of Health &Family Welfare	Member
4	Finance Secretary to Government / Representative	Member
5	Director General, Drugs Control Administration	
6	Director Medical Education	Member
7	Director of Public Health &Family welfare	Member
8	Commissioner of APVVP	Member

The Committee shall be responsible for the following:

i. To evaluate commercial bids of technically qualified bidders.

ii. To decide the award of contract or rate contract to technically qualified bidders offering the most competitive rates

iii. To decide upon any other matters relating to the procurement

Government hereby name the program as ÄNNA SANJIVINI", Dept. of HM&FW shall operationalise and run the program, the Department of Rural Development and Department Municipal Administration shall provide assistance as far as SHG / MEPLMA issues are concerned.

(BY ORDER AND IN THE NAME OF THE GOVERNOR OF ANDHRA PRADESH)

POONAM MALAKONDAIAH
PRINCIPAL SECRETARY TO GOVERNMENT

To
The MD, APMSIDC, AP., Hyderabad.
The Commissioner of Family Welfare, AP., Hyderabad.
The CEO, SERP, AP., Hyderabad.
The CEO, MEPMA, AP., Hyderabad.
The DME, A.P., Hyderabad.
The DPH, AP., Hyderabad.
The Commissioner of APVVP., AP., Hyderabad.
The DG, D&C, DCA, AP., Hyderabad.
The MA&UD Department, A.P.Secretariat, Hyderabad
The PR&RD Department, A.P.Secretariat, Hyderabad
Copy to:
The Prl. Secretary to C.M.
The P.S. to M(HM&FW)
The PS. to Prl. Secretary to HM&FW.
The PS to Prl. Secy. to MA&UD Department,
The PS to Prl. Secy. to PR&RD Department
SF/SC.

//FORWARDED::BY ORDER//

SECTION OFFICER